K020003
p1/2

510(k) SUMMARY

Submitted For:	BIO PROTECH INC. 303 Boryung B/D 37-10 Kangnam Ku, Seoul, Korea 135-090
Submitted by:	TUCKER & ASSOCIATES Official Correspondent and United States Agent for Bio Protech Inc. JANNA P. TUCKER, President – CEO 198 Avenue de la D'emerald Sparks, NV 89434 Phone: 775-342-2612 Fax: 775-342-2613 E-mail: Tuckerjan@aol.com
Date of Submission:	NOV 7 2002
Classification Name:	ELECTRODE, ELECTROCARDIOGRAPH Product Code: DRX Class II Device
Proprietary Name:	(Multiple Labels) Telectrode ECG Electrode
Common Name:	ECG Electrode
Regulatory Reference:	CFR 870.2360
Predicate Device:	Skintact™ ECG Electrodes (K982521)
Labels/Labeling:	This device will be marketed to medical device suppliers, Dentist and Doctor Offices, Clinics, Emergency Response Professionals, Hospitals and other healthcare professionals for the Intended Use purposes below, and will be appropriately labeled in accordance with Title 21 CFR Part 801.
Intended Use:	An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.

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Description:	Bio Protech electrodes are self-adhesive, non-sterile, single use disposable ECG electrodes. All include an Ag/Agc l sensing element and the solid adhesive hydro gel has very low impedance level. Most importantly, the adhesive gel sticks on both skin of patient and the sensing element so that the movement artifact can be significantly lowered. The adhesive qualities of the foam is strong enough to use for stress test and holter.
Substantial Equivalence:	This device is equivalent to those in commercial distribution for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Both in its intended use and/or physical characteristics, this device is equivalent to devices currently marketed by U.S. companies. It is **substantially equivalent** to the device manufactured by Leonhard Lang GmbH under K982521.
Performance Summary:	The electrical performance of BIO PROTECH ECG electrodes meets the requirements of the Medical Devices Directive: EU Council Directive 93/42/EEC, ANSI/AAMI ec12-2000, and has been issued a Certificate of Conformity (01-KOR-MDD-0003)
Biocompatibility Testing:	The biological safety of the PRO TECH ECG electrodes has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The tests were selected on the basis of ISO 10993-1, Biological Evaluation of Medical Devices – Part 1 – Guidance on selection of tests.
Shelf Life:	Data obtained in real time shelf life studies was reviewed and found to substantiate the 24 month shelf life claim.
Conclusion:	This device is substantially equivalent to the device approved as K982521.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Bio ProTech, Inc.
c/o Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D'emerald
Sparks, NV 89434-9550

Re: K020003
Trade Name: Electrocardiograph (ECG) Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: August 6, 2002
Received: August 9, 2002

Dear Ms. Tucker:

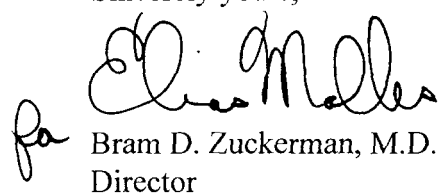
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

APPLICANT: **BIO PROTECH, INC.**

510(k) NUMBER: K020003

DEVICE NAME: **ELECTROCARDIOGRAPH (ECG) ELECTRODE**

ECG electrodes are used to record the following ECGs from a patient: Resting ECG, Exercise ECG and/or ambulatory (Holter) monitoring.

The intended patient population can be adult, pediatric and neonatal, while the environment of use can be hospital (or clinic), ambulance, or daily use environment (for Holter monitoring).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elsa Mallis

Division of Cardiovascular & Respiratory Devices

510(k) Number K020003

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

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